K063277



EPMedSystems

# 510(k) Summary

NOV 30 2006

**Summary preparation date:** 10/26/06

## 1.0 Device Trade Name

| | |
|---|---|
| EP-WorkMate® | Programmable Diagnostic Computer |

## 2.0 Establishment Address and Registration

**EPMedSystems, Inc.**
Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, NJ 08091-9293 USA
Larry Picciano
Telephone: 856-753-8533
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E-mail: lpicciano@epmedsystems.com

US Food and Drug Administration Establishment Registration No.:2248049

## 3.0 Device Classification

Programmable diagnostic computers have been classified as Class II, 74 DQK. No performance standards have been established under CFR 21 Part 870.1425 or Section 514 of the Food, Drug, and Cosmetic Act for programmable diagnostic computers.

## 4.0 *Predicate Devices / Technology

| | | |
|---|---|---|
| EP-WorkMate® | K994011 | 03/23/00 |
| Carto RMT EP Navigation System | K042681 | 09/29/05 |
| Carto XP EP Navigation System Software Version 8 | K042999 | 03/21/05 |
| Carto EP and Qwickmap EP Navigation System | K020863 | 01/09/03 |
| Carto XP EP Navigation System | K013083 | 11/21/01 |
| Carto EP Navigation System | K000248 | 05/05/00 |
| Modification to Carto EP Navigation System | K000190 | 05/05/00 |
| Modification to Carto EP Navigation System | K993729 | 12/03/99 |
| Carto EP Navigation System | K992968 | 09/29/99 |

| | | |
|---|---|---|
| Carto System | K954395 | 12/21/95 |

* This application describes a modification to the EP-WorkMate® called MapMate™.

## 5.0 Labeling and Intended Use

The following labeling is contained within **Appendix 4**.

5.1 Proposed Marketing Literature

5.2 Proposed Instructions for Use Manual

5.3 **Intended Use**

The EP-WorkMate® system with an EP-4 stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of refractory measurements, initiation and termination of tachy-arrhythmias, measurements of electrical conduction, and arrhythmia mapping.

## 6.0 Indications for Use

**Indications for Use Statement**

EP-WorkMate® is indicated for use during clinical electrophysiology procedures.

## 7.0 Device Description

7.1 **EP-WorkMate® Overview:** Cardiac EP studies are diagnostic tests that enable physicians to look at electrical signals from within the heart in detail to determine if an abnormality (arrhythmia) exists. The cardiac EP laboratory is typically equipped with multiple stand-alone systems used in EP studies such as recording, mapping, navigation, and imaging (e.g., fluoroscopy) systems. Because the systems are not interconnected the data is not synchronized and the reports are disparate. Lack of integrated reports causes clinicians to enter the same patient data into each system and to try to accurately annotate events in each system's log during EP studies. The EP lab is staffed with one or more physicians, nurses, and technologists thus making the lab a busy and sometimes crowded workspace. A physician directs the EP study and the operation of the EP-WorkMate® system; some physicians operate the system, others direct a member of the clinical staff on the system operation. The EP-WorkMate® system is illustrated in **Figure 1**. Under the direction of a physician, the cardiac stimulator delivers diagnostic stimuli to the heart through the EP catheter(s). The heart's electrical response to the diagnostic signals is returned through the catheter(s) to the amplifier/signal conditioning unit. The amplified and conditioned signals are displayed as waveforms and tabular EP data on the EP-WorkMate® real-time display monitor for diagnosis by the physician. A physician may also choose to record/store the signals using the EP-WorkMate®.

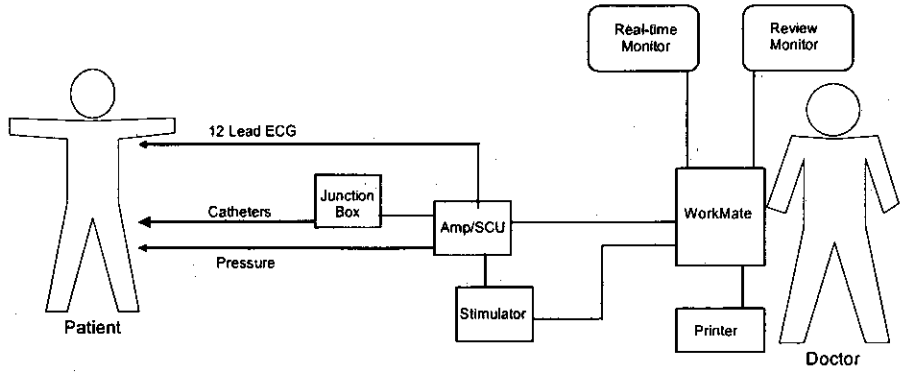


**Figure 1: EP-WorkMate® System Block Diagram**

7.2 **CARTO™ XP Navigation System (K042681) Overview:** Biosense Webster's CARTO™ EP Navigation System is a position mapping system. The CARTO™ system acquires, analyzes, displays electroanatomical maps of the heart and provides real-time display of catheter tip position superimposed on 3D cardiac maps. A magnetic field called the mapping area is created by the CARTO™ electromagnetic location pad. The location pad is carefully positioned under the patient table so that the accurate mapping area is centered on the patient's heart. Mapping catheter(s) equipped with magnetic position sensors are moved by the physician through the patient's heart. Depending on the physician's choice either discrete positions or a series of catheter positions comprising a map is recorded in the CARTO™ system. The position data is acquired simultaneously with intracardiac (IC) electrograms. The CARTO™ system combines the position and IC data and renders electroanatomical maps of the heart. The CARTO™ system is illustrated in **Figure 2**.

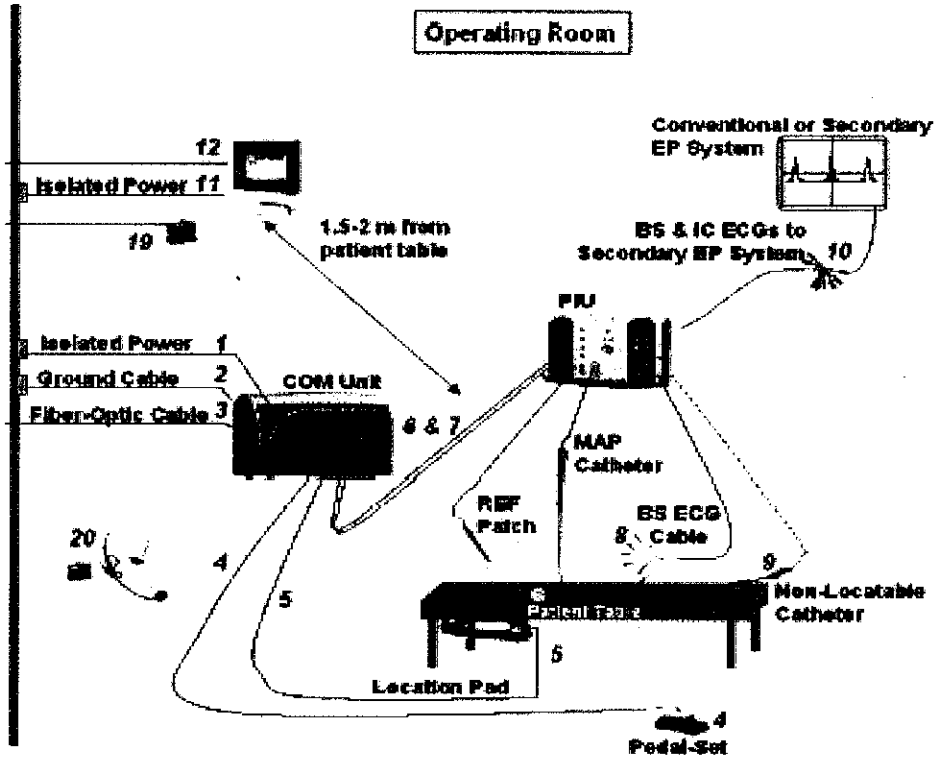


**Figure 2: CARTO™ XP Navigation System**

7.3 **General description of MapMate™:** This application describes a modification to the EP-WorkMate® system that will be offered as an option to customers under the name MapMate™. MapMate™ is comprised of a software module and an electronic interconnection between the EPMedSystems EP-WorkMate® and the BioSense Webster CARTO™ XP Navigation System computer. When the MapMate™ option is utilized, clinicians enter patient data in one system instead of two. A procedure log is created containing the list of map points along with the EP signals. Therefore, valuable time and attention are conserved in the busy EP lab enabling clinicians to focus on the EP case. The interconnection of MapMate™ to EP-WorkMate® is illustrated in **Figure 3**. **Figure 4** illustrates one of MapMate's™ graphical user interfaces (GUI); CARTO™ and WorkMate® waveforms are displayed.

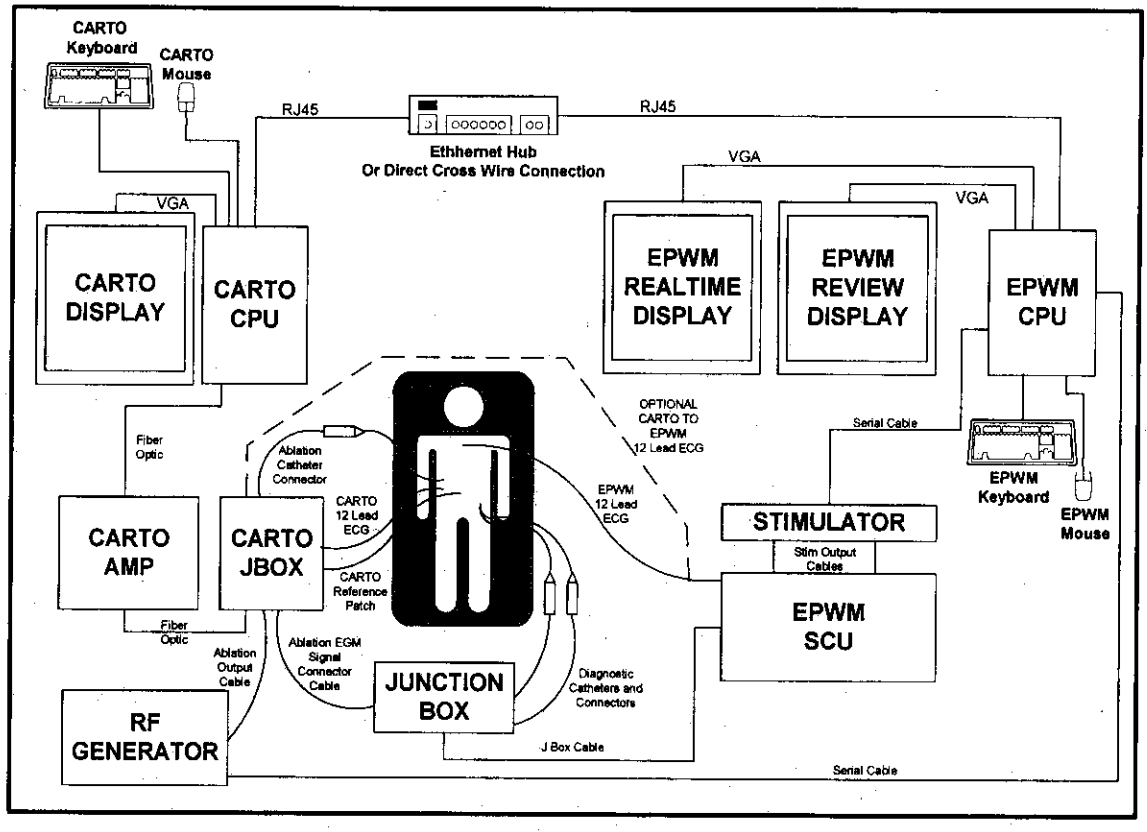


**Figure 3: EP-WorkMate® with MapMate™ Block Diagram**

7.4 **MapMate™ software description:** The MapMate™ for EP-WorkMate® software is a simple add-in to the EP-WorkMate® application software. The CARTO™ XP library software was supplied to EPMedSystems by Biosense Webster and was interfaced to MapMate™ by EPMedSystems. The EP-WorkMate® and MapMate™ software was modified using the same Microsoft Visual C++ 6.0 Integrated Development Environment (with Visual Studio Service Pack 6.0) within which Windows for WorkMate® was developed. The MapMate™ for EP-WorkMate® software command structure allows the EP-WorkMate® to receive messages when the CARTO™ adds, edits or deletes a map point, selects a map point, requests patient demographics and transmits a JPEG image. A list comprising a functional software comparison between EP-WorkMate® and MapMate™ is presented in **Table 1**.

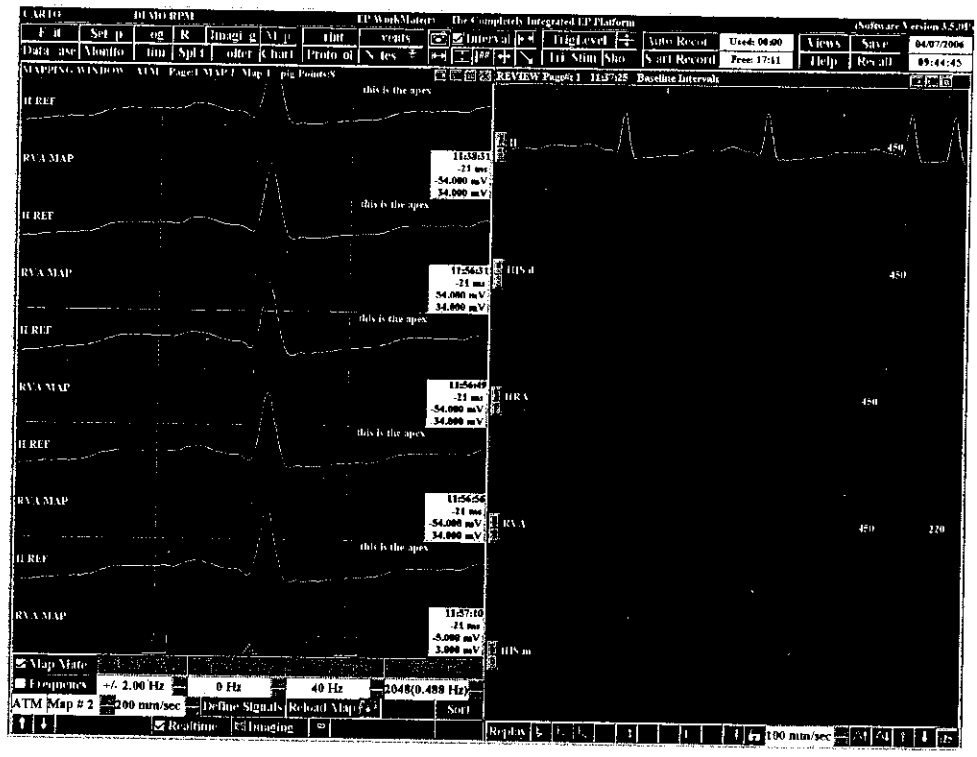

**Figure 4: MapMate™ Graphical User Interface**

7.5 **MapMate™ hardware description:** The MapMate™ option does not require any hardware changes in the EP-WorkMate®. Similarly, there is no change in the form factor of the EP-WorkMate® System.

7.6 **EP-WorkMate® with MapMate™ connection:** To use MapMate™ as intended, it must be connected to the EP-WorkMate® through a single basic electronic interconnection.

7.6.1 **PC-to-PC connection:** The interconnection between the two computers illustrated in **Figure 3** is required for communication. The hardware interconnection between the computers is comprised of off-the-shelf category five (CAT 5) network cabling; the connections are terminated with standard data communication connectors (RJ-45). LAN connectivity is established using standard networking software protocol, Telecommunications Protocol/Internet Protocol (TCP/IP).

**End of document**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 30 2006

EPMedSystems, Inc.
c/o Mr. Larry Picciano
Director of Regulatory Affairs
Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, NJ 08091-9293

Re: K063277
Trade Name: EP-WorkMate® with MapMate™
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: October 30, 2006
Received: October 31, 2006

Dear Mr. Picciano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmey

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EPMedSystems

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# Indications for Use

510(k) Number (if known): K063277

Device Name: MapMate™

Indications For Use: MapMate™ is indicated for use during clinical electrophysiology procedures.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Volmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063277



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